

## Report Documentation Page

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14. ABSTRACT

**NTRODUCTION: The impact of energy drinks on the cardiac rhythm remains unknown. QT/QTc interval prolongation has been known to induce life threatening arrhythmias. We sought to determine the impact of 5-Hour Energy shot on the QTc interval after acute and chronic consumption. METHODS: This was a randomized, placebo controlled, crossover study enrolling young healthy volunteers not on any medications. Subjects received the study drink (5 Hour Energy shot or placebo) twice daily separated by approximately 7 hours for the first 7 days. This was followed by a washout period of 6 days and the alternate study drink was consumed for the final 7 days. A 12-lead electrocardiogram (ECG) was performed at baseline, 1, 3 and 5 hours on days 1, 7, 15 and 21. The automated ECG measurements were used for per-treatment and ITT analysis and analyzed using the paired t-test. RESULTS: A total of 24 subjects (29±5.8 years) were included for analysis. QTc values after consumption of a single placebo-dose were 414±18, 413±15, 413±19 and 417±19 milliseconds at baseline, 1, 3 and 5 hours respectively. Post consumption of a single 5 hour Energy dose, QTc values were 415±17, 408±19, 410±20, and 413±17 milliseconds at baseline, 1, 3 and 5 hours, respectively (all time matched inter- group p-values > 0.292). QTc values after consumption of placebo for 7 days were 415±20, 413±18, 409±19, and 413±22 milliseconds at baseline, 1, 3 and 5 hours, respectively. Post consumption of 5 hour Energy for 7 days, resulted in QTc values of 415±22, 413±24, 415±24, and 415±21 milliseconds at baseline, 1, 3 and 5 hours, respectively (all time matched inter- group p-values >0.198 ). There was no difference between the PR interval, QRS duration, QT interval and heart rate between the two groups. CONCLUSION: 5-Hour Energy did not induce any significant changes in the QTc interval or other ECG parameters after single and multiple doses throughout a 7 day period. These results may vary between different energy drinks due to the varying ingredients within them.**

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# Impact of Acute and Chronic 5-Hour Energy Consumption on Electrocardiographic and Blood Pressure Parameters

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## ABSTRACT

**INTRODUCTION:** The impact of energy drinks on the cardiac rhythm remains unknown. QT/QTc interval prolongation has been known to induce life threatening arrhythmias. We sought to determine the impact of 5-Hour Energy shot on the QTc interval after acute and chronic consumption.

**METHODS:** This was a randomized, placebo controlled, crossover study enrolling young healthy volunteers not on any medications. Subjects received the study drink (5 Hour Energy shot or placebo) twice daily separated by approximately 7 hours for the first 7 days. This was followed by a washout period of 6 days and the alternate study drink was consumed for the final 7 days. A 12-lead electrocardiogram (ECG) was performed at baseline, 1, 3 and 5 hours on days 1, 7, 15 and 21. The automated ECG measurements were used for per-treatment and ITT analysis and analyzed using the paired t-test.

**RESULTS:** A total of 24 subjects (29±5.8 years) were included for analysis. QTc values after consumption of a single placebo-dose were 414±18, 413±15, 413±19 and 417±19 milliseconds at baseline, 1, 3 and 5 hours respectively. Post consumption of a single 5 hour Energy dose, QTc values were 415±17, 408±19, 410±20, and 413±17 milliseconds at baseline, 1, 3 and 5 hours, respectively (all time matched inter- group p-values > 0.292). QTc values after consumption of placebo for 7 days were 415±20, 413±18, 409±19, and 413±22 milliseconds at baseline, 1, 3 and 5 hours, respectively. Post consumption of 5 hour Energy for 7 days, resulted in QTc values of 415±22, 413±24, 415±24, and 415±21 milliseconds at baseline, 1, 3 and 5 hours, respectively (all time matched inter- group p-values >0.198 ). There was no difference between the PR interval, QRS duration, QT interval and heart rate between the two groups.

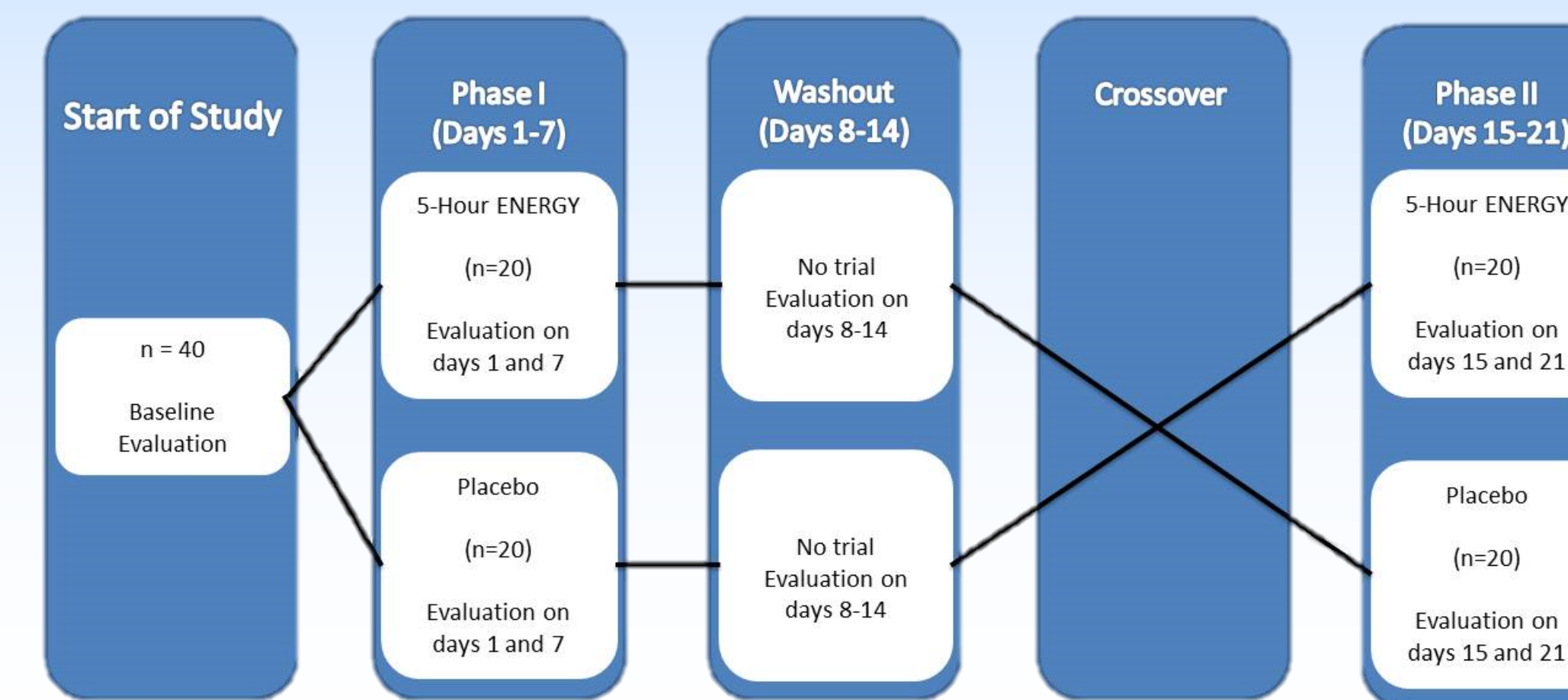
**CONCLUSION:** 5-Hour Energy did not induce any significant changes in the QTc interval or other ECG parameters after single and multiple doses throughout a 7 day period. These results may vary between different energy drinks due to the varying ingredients within them.

## INTRODUCTION

- From 2008 to 2012, the market for energy drinks increased by 60%, resulting in sales of more than \$12.5 billion.
- The number of emergency department visits involving energy drinks has been steadily rising from 10,068 in 2007 to 20,738 in 2011. Of those visits, 58% involved only energy drinks while the remaining 42% involved energy drinks in combination with other substances.
- There have been reports of atrial fibrillation, Takotsubo cardiomyopathy and sudden cardiac deaths in healthy individuals after energy drink consumption.
- The FDA does not regulate nutraceuticals as rigorously as new drug entities and the safety of energy drink consumption needs further exploration.
- The goal of this study is to assess the acute and chronic effects of 5-Hour Energy consumption on electrocardiographic and hemodynamic parameters in healthy human subjects.

## METHODS

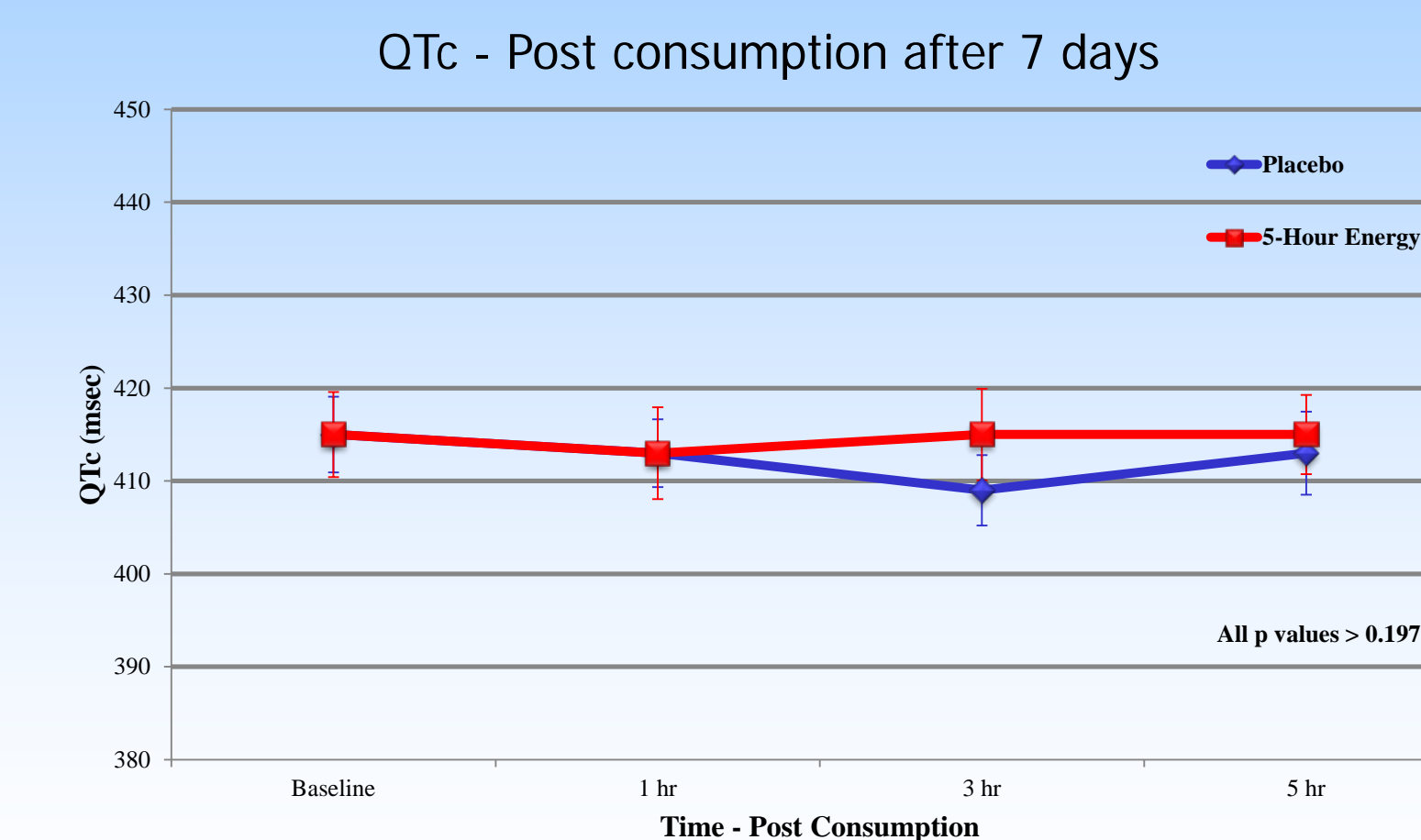
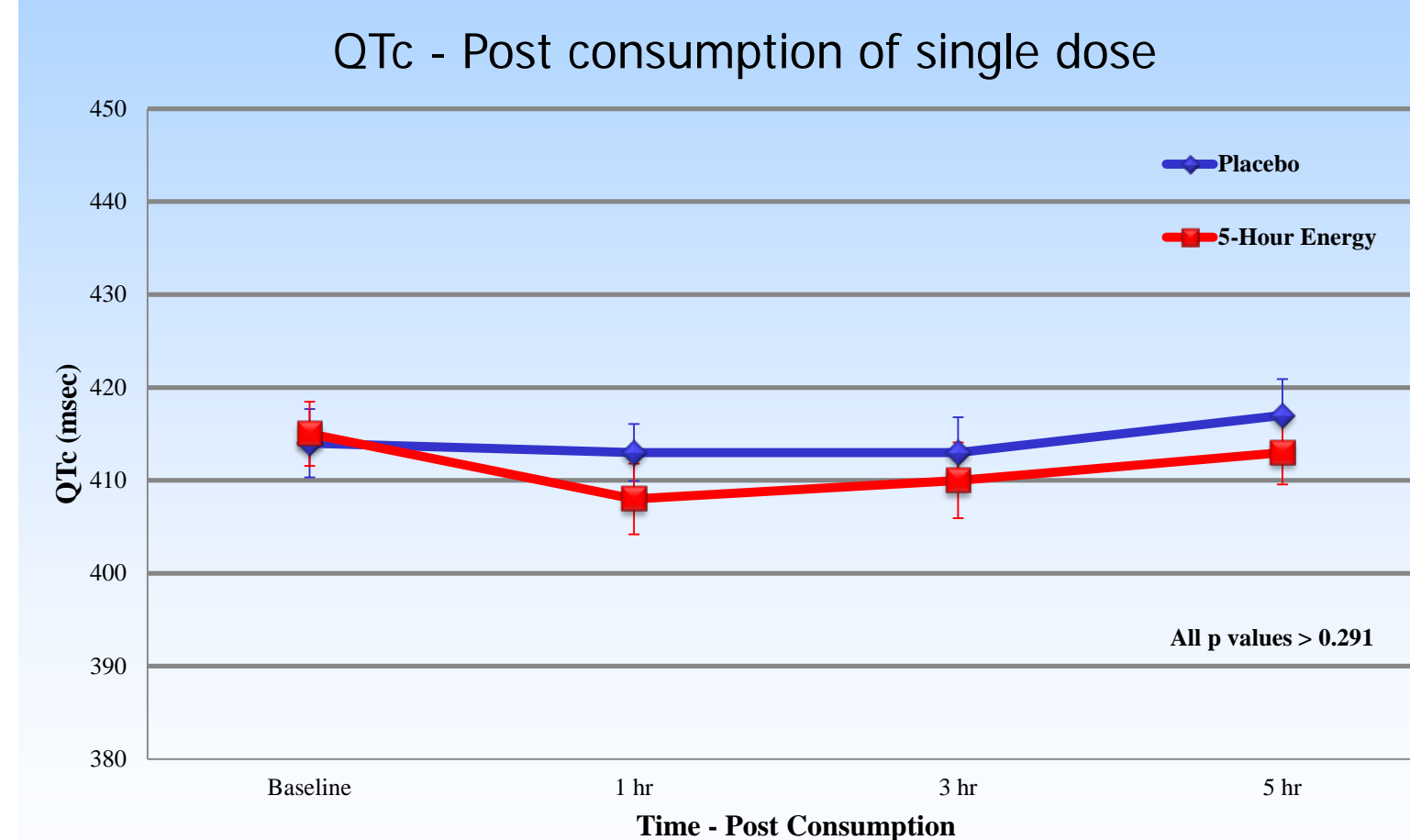
- This was a randomized, double blind, placebo-controlled, crossover study.
- This study planned to enroll 40 subjects.
  - Inclusion Criteria: healthy individuals between 18 and 40 years of age.
  - Exclusion Criteria: abnormal baseline cardiac rhythm, history of atrial or ventricular arrhythmia, baseline corrected QT (QTc) interval greater than 440 milliseconds (msec), concurrent use of drugs potentially interacting with either 5-Hour Energy drink or effecting electrocardiographic or hemodynamic parameters, or having consumed any type of energy drink within one week prior to randomization.
- Endpoints: QTc interval, office systolic blood pressure (SBP), office diastolic blood pressure (DBP), ambulatory SBP and DBP, PR interval, QRS complex duration and heart rate.
- Intervention: 2 shots separated by 7 hours of either 5-Hour Energy or matching placebo daily for 7 days.
- 12-lead ECG and office blood pressure were measured at baseline and at 1, 3 and 5 hours post consumption on days 1, 7, 15 and 21.
- Intergroup comparisons were performed using a paired student's t-test.



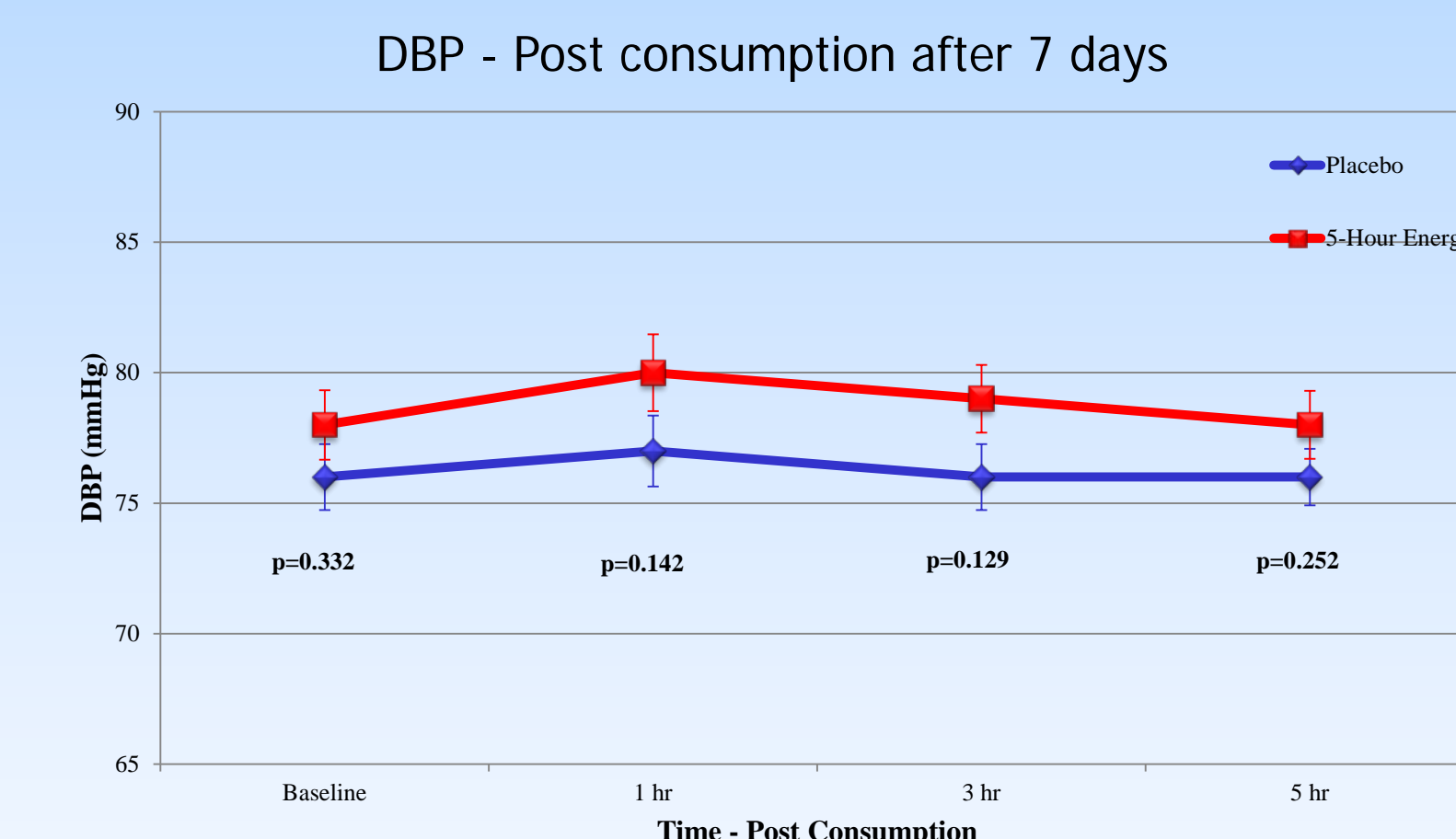
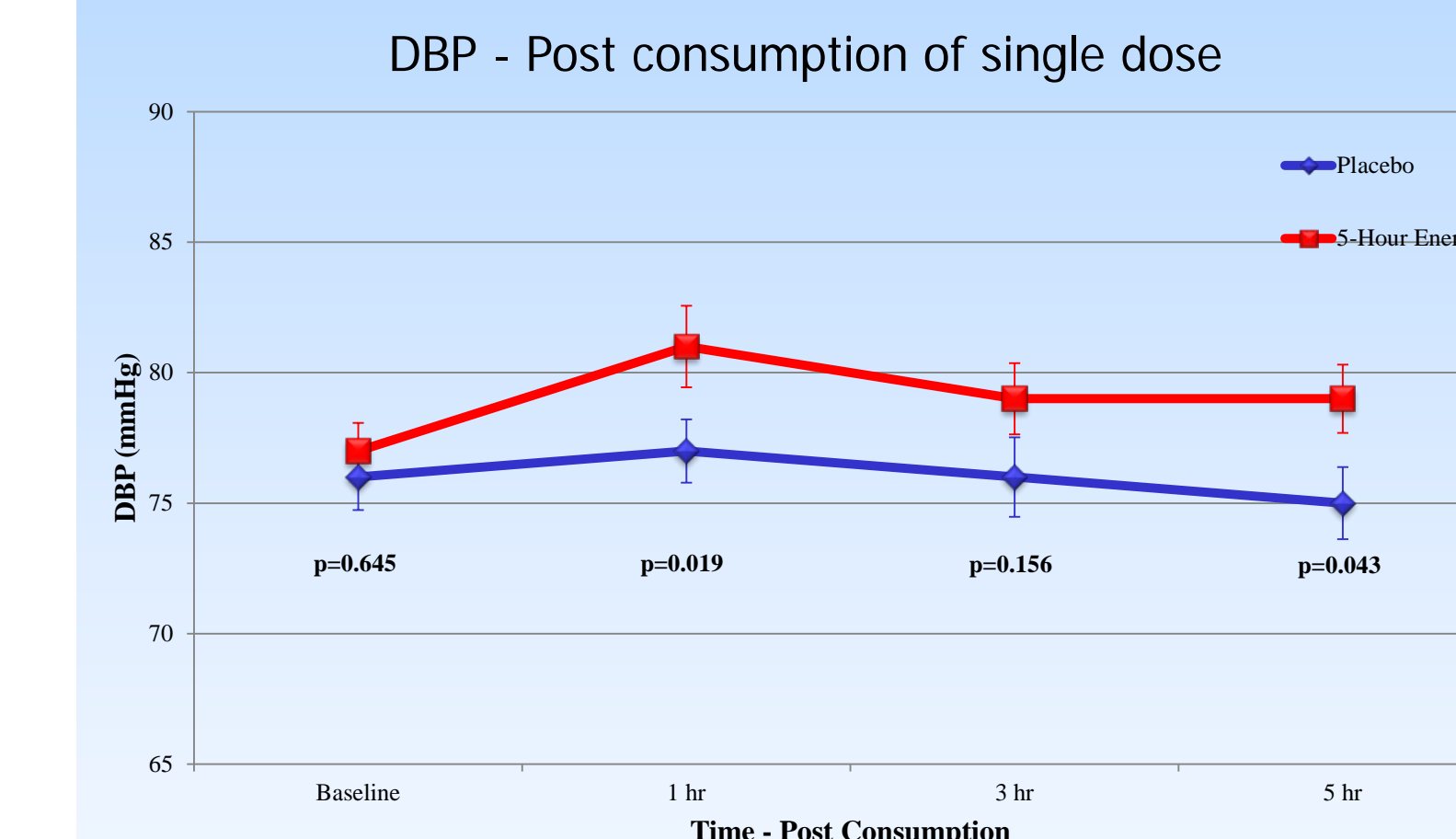
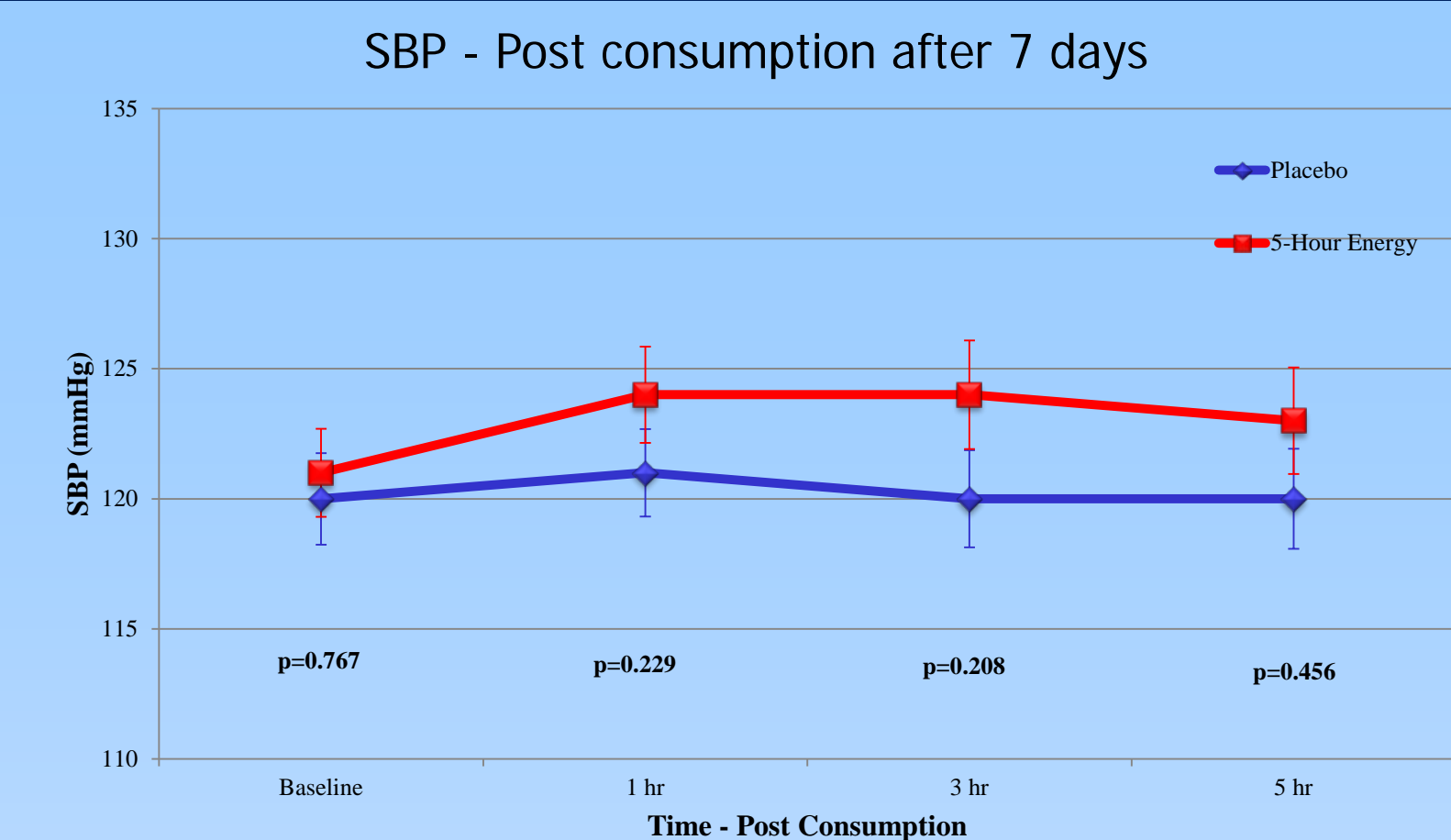
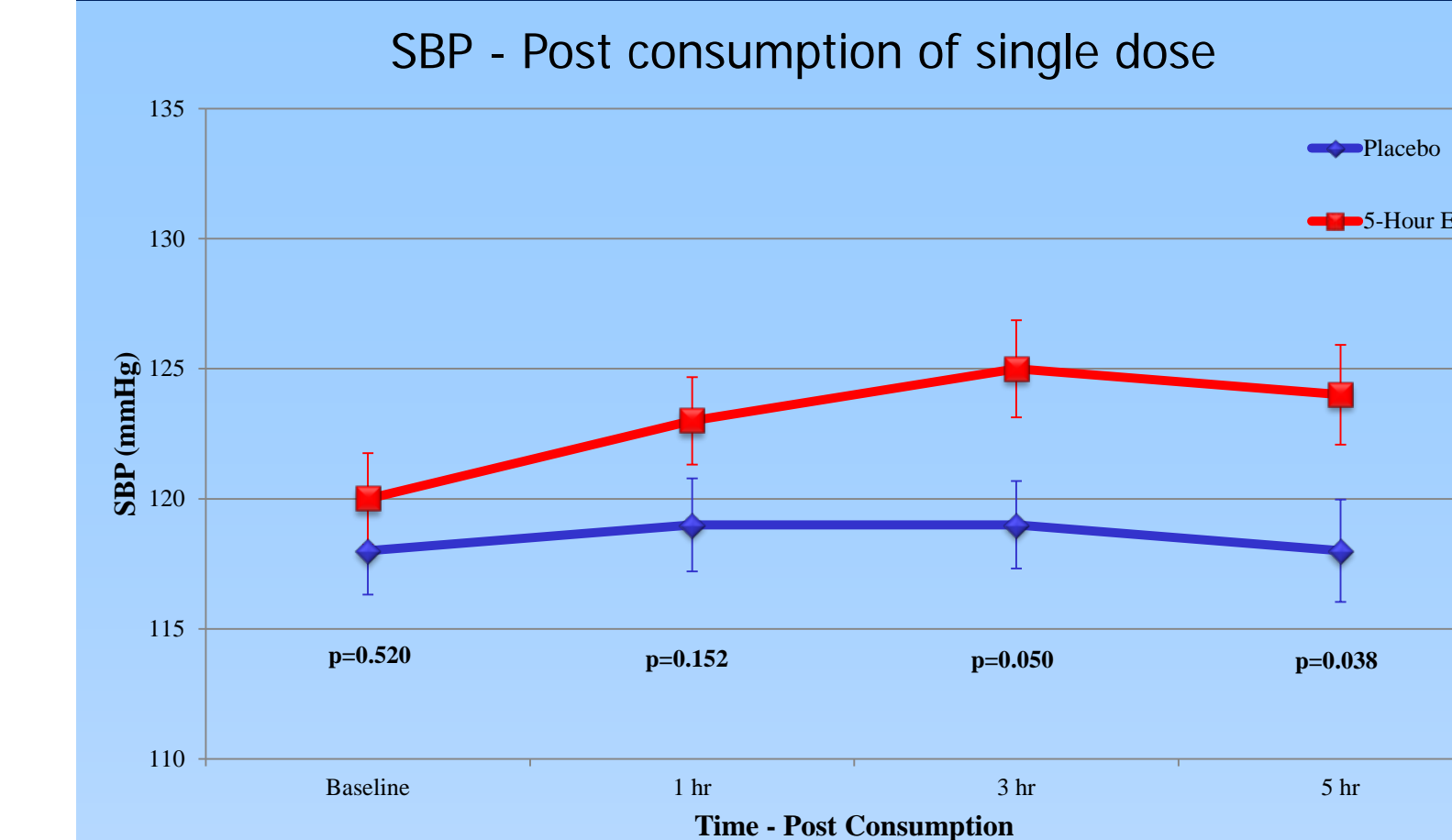
## RESULTS

Twenty four subjects were included for analysis:

- Age: 28.4 ± 5.8 years
- Weight: 167.2 ± 30.1 lbs
- Height: 68.4 ± 3.6 inches
- Male: 77.8%
- Caucasian: 77.8%



## RESULTS



Maximum post-dosing change from placebo	Change (p-value)
QTc interval (Day 1)	-5±18 msec (p=0.307)
QTc interval (Day 7)	6±20 msec (p=0.114)
Systolic blood pressure (Day 1)	4±8 mmHg (p=0.034)
Systolic blood pressure (Day 7)	3±5 mmHg (p=0.053)
Diastolic blood pressure (Day 1)	2±4 mmHg (p=0.031)
Diastolic blood pressure (Day 7)	3±4 mmHg (p=0.243)

Differences in PR interval, QRS duration and heart rate between the two groups were non-significant.

## CONCLUSIONS

- 5-Hour Energy did not significantly prolong the QTc interval or any other ECG parameters after a single shot or post 7 days of consumption.
- A single dose of 5-Hour Energy significantly increased SBP and DBP but the effects appear to diminish with chronic consumption.
- Future studies are needed to further assess the cardiac effects of energy drinks using differing products, doses, populations and duration of consumption.